

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TWINSTRAND BIOSCIENCES, INC. &
UNIVERSITY OF WASHINGTON,

Plaintiff,

v.

GUARDANT HEALTH, INC.,

Defendant.

C.A. No. 21-1126-GBW-SRF

PUBLIC VERSION OF D.I. 599

FILED: MARCH 10, 2025

**DEFENDANT GUARDANT HEALTH, INC.'S REPLY BRIEF IN SUPPORT OF ITS
MOTION FOR RELIEF UNDER FED. R. CIV. P. 60(B)**

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. ARGUMENT	2
A. Plaintiffs’ Statements to The PTO in its <i>Ultra Vires</i> Petition Disclaimed Y-Adapter Arms Not Used in Combination With a Barcode Sequence	2
B. Plaintiffs Misrepresent The Trial Record	4
C. Guardant’s Timely Motion Properly Relies on “Newly Discovered Evidence”	8
D. Guardant’s Motion Does Not Support Plaintiffs’ Request For Enhanced Damages.....	10
III. CONCLUSION.....	10

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Amado v. Microsoft Corp.</i> , 517 F.3d 1353 (Fed. Cir. 2008).....	10
<i>Amado v. Microsoft Corp.</i> , C.A. No. SA CV 03-242 DOC (ANx), 2007 WL 9837821 (C.D. Cal. Mar. 13, 2007)	10
<i>Brown v. Pennsylvania R. Co.</i> , 282 F.2d 522 (3d Cir. 1960).....	9
<i>Chilson v. Metropolitan Transit Authority</i> , 796 F. 2d 69 (5th Cir. 1986)	9
<i>Henriquez v. Astrue</i> , 499 F. Supp. 2d 55 (D. Mass. 2007)	9
<i>In re Hertz Global Holdings, Inc. Sec. Litig.</i> , 830 F. Appx. 393 (3rd Cir. 2020)	9
<i>Johnson v. Life Ins. Co. of N. Am.</i> , 626 F. App’x 379 (3d Cir. 2015)	9
<i>Limon v. Double Eagle Marine, L.L.C.</i> , 771 F. Supp. 2d 672 (S.D. Tex. 2011)	9
<i>PACT XPP Schweiz AG v. Intel Corp.</i> , No. 19-1006-JDW, 2024 WL 3552521 (D. Del. July 26, 2024).....	3
<i>Rosebud Sioux Tribe v. A & P Steel Inc.</i> , 733 F.2d 509 (8th Cir. 1984)	9
<i>TDM Am., LLC v. U.S.</i> , 100 Fed. Cl. 485 (2011)	10
Rules	
Rule 60	1, 4, 8, 9
Rule 60(b)	8, 9
Rule 60(b)(2).....	1, 2, 9, 10
Rule 60(b)(5).....	2, 10
Rule 60(b)(6).....	10

I. INTRODUCTION

Plaintiffs twist the record of who said what in front of the Patent Office and this Court. Guardant’s Rule 60 motion should be granted.

First, Plaintiffs cannot escape the fact they filed an *ultra vires* petition asserting that the Patent Office would be acting beyond its authority if it were to exclude barcodes from the claimed “strand distinguishing nucleotide sequence.” Plaintiffs now backpedal, stating that they told the Patent Office during reexamination of the ’631 patent what a “strand distinguishing nucleotide sequence” “*can* be” (D.I. 595 “Opp’n” at 9) (emphasis added). But the reexamination record (including both the clear and unmistakable statements by Plaintiffs and the context of those statements) establishes that Plaintiffs actually told the Patent Office what “strand distinguishing nucleotide sequence” *must* be—a Y-shaped adapter in combination with a barcode. Plaintiffs’ attempt to cast aside the import of their own representations to the Patent Office and to shift the focus to Guardant’s statements fail, in part because (as Plaintiffs point out) it is statements “by the patentee” that are most relevant to disclaimer.

Second, Plaintiffs misrepresent the trial record, pointing to testimony and demonstrative slides showing that Dr. Pachter referenced barcodes at trial. But none of those references were in the context of the claim limitation at issue here: “strand distinguishing nucleotide sequence.” Plaintiffs introduced no evidence that *this limitation* was met by the arms of the Y-shaped adapter in combination with a barcode, and therefore the jury had no basis to find infringement under the construction required by Plaintiffs’ disclaimer.

Third, Plaintiffs wrongly claim that Guardant’s motion is untimely and improper. Guardant was diligent in bringing the motion and took efforts to avoid burdening the Court with unnecessary motion practice. And with regard to the “newly discovered evidence” requirement of Rule

60(b)(2), although Plaintiffs’ petition arose after trial, it revealed a fact—Plaintiffs’ true understanding of the claim term—that existed at the time of trial (Opp’n at 4). Even if the Court agrees with Plaintiffs that the *ultra vires* petition is not properly defined as newly discovered evidence under Rule 60(b)(2), vacatur of an award of future royalties under Rule 60(b)(5) is proper here, where an ongoing, prospective royalty award is not equitable.

Finally, Plaintiffs’ request for fees and enhanced damages should be rejected for the reasons in Guardant’s post-trial briefing. D.I. 548. Plaintiffs’ bare reference to Guardant’s motion as “frivolous” does not change that. Plaintiffs’ shifting position regarding the scope of “strand distinguishing nucleotide sequence” is to blame here, not Guardant’s attempt to hold Plaintiffs to their unequivocal statements.

II. ARGUMENT

A. Plaintiffs’ Statements to The Patent Office in its *Ultra Vires* Petition Disclaimed Y-Adapter Arms Not Used in Combination with a Barcode Sequence

Plaintiffs accused Guardant of mischaracterizing Plaintiffs’ statements to the Patent Office, but Guardant simply quoted Plaintiffs’ statements in its opening brief and attached the *ultra vires* petition containing those statements. Confronted with their own statements about the meaning of the term, Plaintiffs backpedal, stating in their answering brief that they simply told the Patent Office what a “strand-distinguishing nucleotide sequence” “*can* be.” Opp’n at 9 (emphasis added). But this is incorrect. Plaintiffs repeatedly and unequivocally argued that this limitation requires both a Y-shaped adapter and a barcode, leaving out any mention of the fact that at trial, Plaintiffs relied exclusively on the Y-shaped adapter to show that this limitation was met. D.I. 593 at 9 (citing ten statements that the strand-distinguishing nucleotide sequence is the “Y-shaped adapter[] in combination with barcodes”); *id.* at 10-14; D.I. 593 Ex. B, Trial Tr. at 464:15-465:9.

If Plaintiffs had only identified what a “strand distinguishing nucleotide sequence” *could*

be, there would be no basis for arguing collateral estoppel or law of the case (the bases of the *ultra vires* petition). But Plaintiffs argued it would be impermissible for the Patent Office to even consider the meaning of “strand distinguishing nucleotide sequence” because “the district court already resolved the meaning.” D.I. 593, Ex. A at 9. Plaintiffs then asserted ten times that this meaning is “Y-shaped adapters like those containing P5 and P7 in combination with barcodes.”¹

Plaintiffs cannot have it both ways, arguing that the “strand-distinguishing nucleotide sequence” is satisfied by the arms of the Y-shaped adapter *alone* in Guardant’s accused products at trial, and then arguing that the same limitation requires a Y-shaped adapter *in combination with a barcode* to save the claims from invalidity in the reexamination. Plaintiffs’ statements and the context of those statements show that Plaintiffs were telling the Patent Office (and the public) what a “strand-distinguishing nucleotide sequence” is and more importantly, “what it isn’t.” *PACT XPP Schweiz AG v. Intel Corp.*, No. 19-1006-JDW, 2024 WL 3552521, at *5 (D. Del. July 26, 2024).

Rather than directly address the substance of their statements, Plaintiffs spend much of their brief focused on *Guardant’s* statements in response to the *ultra vires* petition. The block quote from Guardant’s response to the petition at page 7 of the Opposition (which Plaintiffs allege undermines Guardant’s motion) is taken out of context. In responding to Plaintiffs’ argument, Guardant merely pointed out that even if, *arguendo*, “strand distinguishing nucleotide sequence” broadly covered both (1) Y-shaped adapters alone and (2) Y-shaped adapters in combination with a barcode, that Loeb still qualified as prior art because the ’631 priority documents lack written description support for the full claim scope. D.I. 596, Ex. 1 at 6-8.

Guardant’s response is entirely consistent with the point Guardant makes here: that

¹ Contrast the Court’s actual ruling, that Plaintiffs were “not estopped” from this argument. D.I. 593-3, Ex. C at 6. Plaintiffs abandoned any such argument at trial. D.I. 593 at 4-5.

Plaintiffs' *ultra vires* petition does not argue the claim limitation is satisfied by only P5/P7 of the Y-adapter, as it did at trial, but instead construes "strand distinguishing nucleotide sequence" to encompass both the P5 and P7 sequences and the barcode. *See also* D.I. 593, Ex. A at 12. In the second paragraph of the introduction of its opposition, Guardant stated:

As an initial matter, Patent Owner inappropriately uses this petition to advance, under the guise of estoppel, a construction inconsistent with its position in district court. In district court, Patent Owner argued that P5 and P7 alone satisfied the "strand-distinguishing nucleotide sequence" limitation,' whereas here Patent Owner maps the limitation to P5 and P7 *in combination with a barcode*.

D.I. 596, Ex. 1 at 2 (emphasis in original). Plaintiffs' argument that Guardant, seven pages later, somehow contradicted one of its lead arguments is wrong and makes little sense. The sections of Guardant's response to the petition that address the question at issue here (which Plaintiffs ignore) present Plaintiffs' disclaimer exactly the same way. *See, e.g., id.* at 10 ("Patent Owner now newly argues that it is P5/P7 *in combination* with barcodes that forms the strand distinguishing sequence of the claims." (emphasis in original)); *id.* at 12 ("Patent Owner now newly argues" that "the claimed strand-distinguishing sequence *requires* a barcode" (emphasis added)). Thus, even if Guardant's statements were relevant to disclaimer (they are not), they are entirely consistent with Guardant's Rule 60 argument: Plaintiffs have repeatedly twisted the meaning of the claims to suit their objective, and have now settled on a construction that *requires* the "strand-distinguishing nucleotide sequence" to include Y-shaped adapters in combination with barcodes.

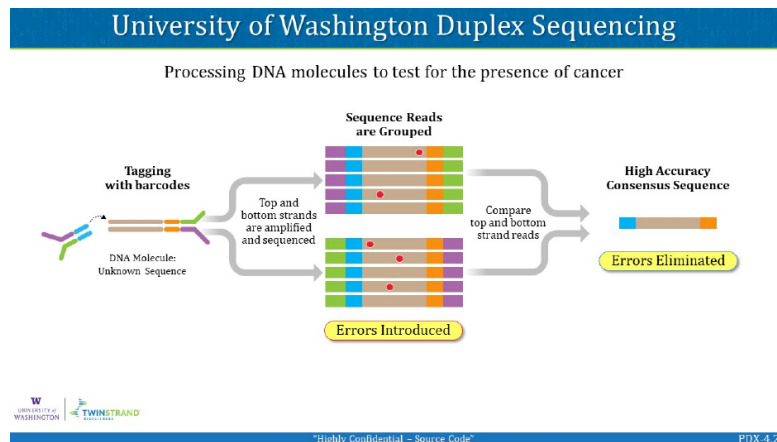
B. Plaintiffs Misrepresent the Trial Record

Plaintiffs attempt to obscure the issue of how they and their expert told the jury that "strand distinguishing nucleotide sequence" was met *solely* by the arms of the Y-shaped adapters in Guardant's accused products. D.I. 593 Ex. B, Trial Tr. at 465:3-9. Rather than identify any instance where Dr. Pachter testified that the "strand distinguishing nucleotide sequence" included both the Y-shaped adapter *and* barcodes, Plaintiffs point to Dr. Pachter's testimony regarding the

use of barcodes generally. While it is true that Dr. Pachter described Guardant’s use of barcodes, he did not do so with respect to the claim element “strand distinguishing nucleotide sequence,” which he unequivocally equated with the arms of the Y-adaptor.

Plaintiffs point to several pieces of testimony and evidence, but none demonstrate that Plaintiffs advanced an infringement theory at trial that Y-shaped adapters in combination with barcodes met the “strand distinguishing nucleotide sequence” limitation.

Plaintiffs first point to Dr. Pachter’s diagram that he made “just to show at a high level how this invention works.” Opp’n at 11-12; D.I. 521 at PDX-4.21; Ex. F, Trial Tr. 396:10-12.



This demonstrative and Dr. Pachter’s associated testimony is merely a general technology overview, not an infringement analysis of either asserted patent, let alone one pertinent to the specific limitation at issue here. The slide itself refers to “University of Washington Duplex Sequencing,” not Guardant or its products. Dr. Pachter testified that by attaching the barcode to a DNA molecule, “you’ll be able to go back and find those barcodes for a lot of different molecules and be able to tell, oh, all those sequences were from the same molecule.” Ex. F, Trial Tr. 397:1-8; *see also id.* at 397:10-19 (“You got to go back and figure out which sequences were actually from the same molecule, and the barcodes, these barcodes, the blue and orange, they let you do that.”). In other words, he described that the function of the barcode is to track entire molecules,

not top and bottom strands. He did not describe the use of Y-shaped adapters and barcodes used *in combination* to distinguish top and bottom strands from the same DNA molecule. Plaintiffs also point to Dr. Pachter's testimony at Trial Tr. 399:9-16. Again, Dr. Pachter here is providing a high-level description of Plaintiffs' method that is not tied to any specific claim element. But Plaintiffs did not claim a particular *method* of distinguishing the strands; in order to get around prior art, they added a requirement that the adapters contain a "strand-distinguishing nucleotide *sequence*," and Dr. Pachter was clear that he believed that sequence was limited to the arms of the Y-adapter. Even if Dr. Pachter's technology description was intended to somehow implicate the claims (which it plainly was not), at most he was describing a *method*, not a "strand-distinguishing nucleotide *sequence*." Further, he testified that this demonstrative "is showing you how, after you've done the sequencing, you can use the purple and the green to tell apart the strands." Ex. F, Trial Tr. 399:1-3. The "purple" and "green" portions of the diagram, however, are the Y-shaped adapters *alone*. This is plain from looking at the demonstrative itself.

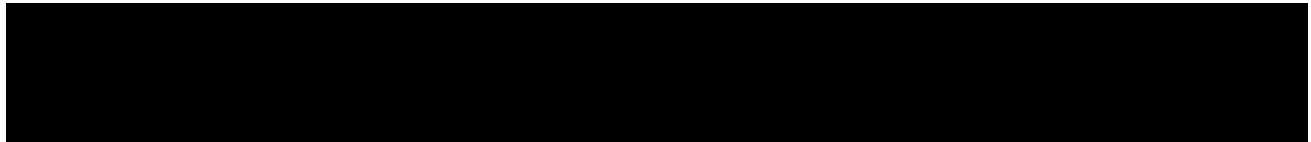
Plaintiffs next point to statements Dr. Pachter made with respect to the claim limitation in subpart (a) of Claim 1: "single molecular identifier (SMI) sequence." Opp'n at 12. But this limitation is distinct from subpart (b) of the claim that recites the "strand distinguishing nucleotide sequence" at issue here. To get around this, Plaintiffs rely on attorney argument, stating that "[f]or subpart (b), and in view of the barcodes already discussed, Dr. Pachter explained that the Y-shaped adapter provides 'the strand distinguishing piece of the invention.'" Opp'n at 12 (citing Trial Tr. 464:18-24). But Dr. Pachter's testimony did not make any such link between the previously discussed barcodes and the Y-shaped adapter for this limitation: he relied on the Y-shaped adapter alone to meet the "strand distinguishing nucleotide sequence" limitation. Plaintiffs cannot point to any trial testimony demonstrating that their infringement theory with respect to the "strand

distinguishing nucleotide sequence” was based on a combination of Y-shaped adapter and barcode.

Plaintiffs then point to another limitation of Claim 1, the “amplifying” step, and refer to PDX-4.104 that shows a “first strand complex” and a “second strand complex.” Opp’n at 13.



Again, Plaintiffs must rely on attorney argument that the Y-shaped adapters are used in combination with the barcodes to provide a strand distinguishing nucleotide sequence, because this is not how Dr. Pachter described this slide. He testified that “



” Ex. F, Trial Tr. 466:11-17. Dr. Pachter makes no mention of Y-shaped adapters or barcodes with respect to this claim limitation.

Plaintiffs then point to evidence related to the and the “separating” step. Opp’n at 13-14. While Dr. Pachter testified that (Ex. F, Trial Tr. 469:6-13),

Plaintiffs identified no such testimony. Finally, Plaintiffs cite PDX-4.115 to show Opp’n at 14. But this slide, and Dr. Pachter’s accompanying testimony, is silent regarding the use of the arms of the Y-shaped adapters in combination with barcodes to meet the “strand distinguishing nucleotide sequence” limitation.



In their brief, Plaintiffs double down on the position they took in reexamination that the Y-shaped adapter works “*in combination with*” barcodes.” Opp’n at 14. But as the record reveals, this is not the infringement theory Plaintiffs advanced at trial.

C. Guardant’s Timely Motion Properly Relies on “Newly Discovered Evidence”

Plaintiffs concede that Guardant’s motion was filed within the one-year period required by Rule 60(b). Opp’n at 16. Nonetheless, Plaintiffs contend that Guardant’s motion should be denied because Guardant did not file immediately upon receiving the *ultra vires* petition.

Plaintiffs’ argument should be rejected for two reasons. First, the timeline of Guardant’s actions is entirely reasonable. Following the receipt of Plaintiffs’ petition in early October 2024, Guardant focused its efforts on a response to that petition, which Guardant filed in mid-October. Thereafter, Guardant began researching and drafting its Rule 60 motion, which was a significant undertaking given the complex existing record regarding the meaning of “strand-distinguishing nucleotide sequence” in this Court and in the Patent Office, and Plaintiffs’ infringement proofs regarding that limitation at trial. Hoping to reduce the burden on the Court, Guardant decided not to rush to file a Rule 60 motion that would be mooted in its entirety if the Court were to grant Guardant’s other pending post-trial motions. Guardant had another good reason to wait to file its Rule 60 motion—giving the Patent Office time to rule on Plaintiffs’ *ultra vires* petition, which

would have provided additional context for the Rule 60 motion. Second, the sole Third Circuit case cited by Plaintiffs is distinguishable. In that case, the movant waited 11 months to file the motion, there was an affidavit introduced that contradicted the movant's explanation for the delay, and the district court had provided an "express warning...to file the Rule 60(b) motion as soon as possible." *Johnson v. Life Ins. Co. of N. Am.*, 626 F. App'x 379, 383-84 (3d Cir. 2015).² In view of the above, the Court should reject Plaintiffs' request to deny Guardant's motion as untimely.

Plaintiffs also attack Guardant's motion on the grounds that the *ultra vires* petition is not "newly discovered evidence" because it did not exist at the time of trial, but Plaintiffs' argument misses the mark. Plaintiffs' case defines "newly-discovered evidence" as "evidence of *facts* in existence at the time of trial." *Brown v. Pennsylvania R. Co.*, 282 F.2d 522, 527 (3d Cir. 1960) (emphasis added). It is plain that although the petition (*i.e.*, the evidence) was not in existence at the time of trial, it reveals Plaintiffs' state of mind regarding the meaning of "strand-distinguishing nucleotide sequence" at trial and before (*i.e.*, the facts). Thus, Rule 60(b)(2) applies. *See In re Hertz Global Holdings, Inc. Sec. Litig.*, 830 F. Appx. 393, 396 (3rd Cir. 2020) (documents created after dismissal of action satisfied Rule 60(b)(2) because they reflected the state of mind of executives at time of trial); *Rosebud Sioux Tribe v. A & P Steel Inc.*, 733 F.2d 509, 516 (8th Cir. 1984) (evidence of perjury arising after trial satisfied Rule 60(b)(2) because the perjury existed during trial and "[i]n fact it was read into evidence at trial"); *Chilson v. Metropolitan Transit Authority*, 796 F. 2d 69, 72 (5th Cir. 1986) (audit created after trial satisfied Rule 60(b)(2) because the audit reflected overpayments that existed at the time of trial); *see also TDM Am., LLC v. U.S.*,

² Because Guardant has provided a reasonable explanation for the timing of its motion, Plaintiffs' other cases are inapposite. *Henriquez v. Astrue*, 499 F. Supp. 2d 55, 57 (D. Mass. 2007) (no explanation provided for delay); *Limon v. Double Eagle Marine, L.L.C.*, 771 F. Supp. 2d 672, 677-78 (S.D. Tex. 2011) (explanation for delay contradicted by filings in related litigation).

100 Fed. Cl. 485, 491 (2011) (post-judgment reexamination proceedings “newly discovered evidence” under 60(b)(2)).³

Even if the Court agrees with Plaintiffs that the *ultra vires* petition is not properly defined as newly discovered evidence under Rule 60(b)(2), Guardant is still entitled to relief. Vacatur of an award of future royalties under Rule 60(b)(5) is proper here, where an ongoing, prospective royalty award is not equitable in view of Plaintiffs’ disclaimer and statements to the Patent Office.

D. Guardant’s Motion Does Not Support Plaintiffs’ Request For Enhanced Damages

For the reasons set forth above, Guardant’s motion is the result of Plaintiffs’ ever-changing claim construction positions. It would not have been necessary had Plaintiffs taken a consistent position regarding the meaning of “strand distinguishing nucleotide sequence” at trial and in the reexamination of the ’631 patent. Plaintiffs, not Guardant, are taking objectively unreasonable positions regarding claim construction and infringement in this litigation.

III. CONCLUSION

For the reasons above and in its opening brief, Guardant respectfully requests that the Court vacate the judgment and enter judgment as a matter of law in favor of Guardant on noninfringement of the ’631 patent. Alternatively, Guardant requests a new trial or relief from ongoing royalties.

³ Plaintiffs’ reliance on the *Amado* case is misplaced for several reasons. First, as Plaintiffs acknowledge, the Federal Circuit applied Rule 60(b)(6), not Rule 60(b)(2) or 60(b)(5) (the sections Guardant’s motion is based on). Opp’n at 18 n.8. Second, the *dicta* in the district court’s decision regarding Rule 60(b)(2) does not have any impact here because the defendant’s motion was not brought within one year of the judgment (unlike Guardant’s motion). *Amado v. Microsoft Corp.*, C.A. No. SA CV 03-242 DOC (ANx), 2007 WL 9837821, at *7 (C.D. Cal. Mar. 13, 2007). And third, the “extraordinary circumstances” standard repeatedly cited by Plaintiffs in their brief is the standard for relief under Rule 60(b)(6), not (b)(2) or (b)(5). *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1363 (Fed. Cir. 2008). Under the properly applied Rule 60(b)(2) and (b)(5) standards, Guardant’s requested relief is justified. D.I. 593 at 10-17.

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Respectfully submitted,

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